The first 100% effective HIV prevention drug is approved and going global

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Not for profit: Gilead, with the Global fund, is waving royalties from the breakthrough drug to reach two million people worldwide

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An epidemic that's been sustained for 44 years might finally be quelled, with the milestone approval of the first HIV drug that offers 100% protection with its twice-yearly injections. It's a landmark achievement that stands to save millions of lives across the globe. The makers are also providing affordable access to the drug in the US and beyond, signing royalty-free licensing agreements with six generic manufacturers to produce and supply it.

In the US, the Food and Drug Administration (FDA) has approved the novel lenacapavir – sold under the brand name Yeztugo – a class of drugs known as capsid inhibitors, which provide almost 100% protection against HIV infection, which currently affects 1.3 million people every year.

In 2024, the journal Science named lenacapavir the Breakthrough Invention of the Year, and we've extensively covered it on its way to market. The pre-exposure prophylaxis (PrEP) provides HIV-negative individuals around 99% protection from contracting the devastating virus through sex.

As we detailed last year, lenacapavir is a capsid inhibitor. In the HIV type 1 (HIV-1) virus, the capsid is a protein shell that houses and protects viral genetic material and is crucial for transporting the virus into a host cell. Once inside the host cell, the capsid is shed, and the virus begins copying itself. Lenacapavir stops that from happening.

“This is a historic day in the decades-long fight against HIV,” said Daniel O’Day, Chairman and Chief Executive Officer of Gilead Sciences on news of the FDA's approval. "Yeztugo is one of the most important scientific breakthroughs of our time and offers a very real opportunity to help end the HIV epidemic.

“This is a medicine that only needs to be given twice a year and has shown remarkable outcomes in clinical studies, which means it could transform HIV prevention. Gilead scientists have made it their life’s work to end HIV and now, with the FDA approval of Yeztugo and in collaboration with our many partners, we can help to make that goal a reality.”

In 2022, lenacapavir was approved – under brand name Sunlenca – to treat HIV in those already infected, but long-acting prevention medication has been much more difficult to realize.

“Yeztugo could be the transformative PrEP option we’ve been waiting for – offering the potential to boost PrEP uptake and persistence and adding a powerful new tool in our mission to end the HIV epidemic,” said Carlos del Rio, MD, Distinguished Professor of Medicine in the Division of Infectious Diseases at Emory University School of Medicine and Co-Director of the Emory Center for AIDS Research in Atlanta. “A twice-yearly injection could greatly address key barriers like adherence and stigma, which individuals on more frequent PrEP dosing regimens, especially daily oral PrEP, can face. We also know that, in research, many people who need or want PrEP preferred less frequent dosing.”

Gilead has also filed for regulatory approval with authorities in Australia, Brazil, Canada, South Africa and Switzerland, with additional applications in the works for Argentina, Mexico and Peru. The company has also made moves to ensure Yeztugo is affordable, with uninsured individuals likely able to access the drug free of cost, if eligible, through its Advancing Access medication assistance program.

Earlier this months, Gilead announced a partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) to supply enough doses of the drug to reach up to two million people over three years in countries supported by the Global Fund, at no profit to the pharmaceutical company. License-free generics of the drug will be manufactured for use across 120 "high-incidence, resource-limited countries, which are primarily low- and lower-middle-income countries."

This crucial access to the drug, which ultimately sets aside profit for people, is a bold move from a pharmaceutical company – but one that recognizes the desperate need to end the global HIV epidemic.

“The agreement between Gilead Sciences and the Global Fund is based on our shared intention to benefit as many people as possible, as quickly as possible with this breakthrough in HIV prevention,” said Daniel O’Day, Chairman and Chief Executive Officer, Gilead Sciences. “We are providing the medicine at no profit to Gilead, and in enough supply to reach up to two million people in low- and lower-middle-income countries ahead of generic lenacapavir becoming available. This is

all part of our unprecedented approach to access for a medicine that could help end the HIV epidemic."

The Global Fund is now working with international organizations to rapidly establish the infrastructure and resources needed to deliver lenacapavir to the middle- and low-income nations most at need.

"This is not just a scientific breakthrough – it's a game-changer for HIV/AIDS," said Peter Sands, Executive Director of the Global Fund. "For the first time, we have a tool that can fundamentally change the trajectory of the HIV epidemic – but only if we get it to the people who need it most. Our ambition is to reach two million people with long-acting PrEP. But we can only do that if the world steps up with the resources required.

"This is a pivotal moment – not just for the fight against HIV, but for the fundamental principle that lifesaving innovations must reach those who need them most – whoever they are, and wherever they live."

Source: Gilead Sciences